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10/615,320	07/07/2003	Rudolf H. Aebersold	66661-055 (P-IS 5661)	9356
41552 7590 04/20/2007 MCDERMOTT, WILL & EMERY 4370 LA JOLLA VILLAGE DRIVE, SUITE 700 SAN DIEGO, CA 92122			EXAMINER HAQ, SHAFIQUL	
			ART UNIT	PAPER NUMBER
			1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/20/2007	PAPER

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If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.



## DETAILED ACTION

### *Response to election/restriction*

1. Applicants' election with traverse of the invention of Group I, claims 1-75, as defined by the first structure of Figure 1, in the reply filed on January 03, 2007 is acknowledged. The traversal is on the ground(s) "that it would not be an undue burden on the examiner to examine additional cleavable groups, functional groups or reactive groups, as disclosed in the specification". This is not found persuasive because a complete search of the invention would include a required search of the entire scope of the composition encompassed by the term "a solid support coupled to a chemical group comprising .... and a reactive group for said sample molecule" as recited in claim 1. A complete search to cover this scope would require burdensome searches in both the technical and patent literature to include all structures covered by the claim language. Claim 1 covers a wide variety of different "cleavable functional groups", "functional groups", "reactive groups" and "solid supports" as described in paragraph 2) b) of the restriction requirement. To encompass all aspects of the composition used in claim 1, searches in multiple subclasses of at least classes 435, 436 and 530 would be required as well as coextensive searches in the technical literature.
2. Claims 1-12, 16, 18-36, 40, 42-50, 52-64, 69 and 71-75 have been examined on the merits to the extent that they encompass the elected invention as defined by the first structure of Figure 1 which contains a "photocleavable group", a "mass tag" and an iodoacetyl reactive group.

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Claims 13-15, 17, 37-39, 41, 51, 65-68 and 70 are withdrawn from further consideration as not being readable on the elected invention. The requirement is still deemed proper and is therefore made FINAL.

***Priority***

3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior applications in the first sentence of the specification. The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 1-12, 16, 18-36, 40, 42-50, 52-64, 69 and 71-75 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the preparation and use of the "solid support" coupled to a "chemical group" as defined by the first structure of Figure 1, does not reasonably provide enablement for a "composition" comprised of a "solid support" coupled to any and all possible "cleavable functional groups", "one or more functional groups" and "reactive groups". The specification

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does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement is present in the specification for the production and use of the "composition" depicted in the first structure of Figure 1. The specification fails to provide an enabling written description, either generic or specific, and commensurate in scope with the claims, of how to prepare and use all "solid supports" coupled to any and all possible chemical structures encompassed by the terms "cleavable functional groups", "one or more functional groups" and "a reactive group" configured in an unspecified relationship to each other. Other than the structure of Figure 1, the specification fails to provide even a minimal generic description of the spatial configuration of the moieties which define the "chemical group", the actual chemical structures involved and how these structures are linked.

There is no enablement in the specification for the step of "modifying said sample" as this term is used in step (b) of claim 52.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Although specific claims may be discussed in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

8. Claims 1-12, 16, 18-36, 40, 42-50, 52-64, 69 and 71-75 are rejected under 35 USC 112, second paragraph, as being indefinite and/or confusing for the following reasons.

a) The chemical structures and the relative configuration of the elements defined as "a cleavable functional group", "one or more functional groups", "a reactive group" and the "solid support" are unspecified in claim 1 thus rendering the claim indefinite as to the exact structures meant to be encompassed by the term "a solid support coupled to a chemical group". The dependent claims which contain variable definitions, for example, such as "tag" as defined in claims 11 and 12, are also indefinite for the reason that the scope of the claims cannot be determined based on a lack of definition of the exact structures meant to be included by the term "a solid support coupled to a chemical group". See also, claims 23 and 52.

b) In claim 1, it is unclear what is meant to be encompassed by the term "one or more functional groups" since the "function" is unspecified. It is also unclear how the "functional groups" differ from the "reactive group" since, according to conventional chemical terminology, a "reactive group" is equivalent to a "functional group". The use of the term "one or more functional groups" is also confusing for the reason that this term is inclusive of "a cleavable functional group", a term which appears earlier in the claim and is apparently intended to define a different moiety.

c) Claim 1 is indefinite and confusing for the reason that the preamble describes "a method for labeling" but no "label" is required in the recited sequence of method steps. It is not clear how the recited sequence of steps would result in the "labeling of a molecule".

d) In claim 2, it is unclear what is meant by the term "second messenger" since no "first messenger" is described and it is unclear what is meant by the term

"messenger". It is also unclear what is meant to be encompassed by the term "metabolite".

e) In claim 1, it is unclear from the term "thereby releasing" what moiety the "sample molecule" is released from.

f) In claim 20, line two, the word "that" should appear after "antibody".

g) In claim 20, it is unclear when the peptide is "isolated" relative to the steps recited in the method. Does the isolation occur prior to the use of the polypeptide as a "sample"? Or does isolation occur as an additional step after "releasing said sample"?

h) In claim 23, it is unclear what is meant by the term "analyzing". It is unclear if the step of "analyzing" involves, for example, the detection of the presence/amount of "sample molecule" or whether additional steps such as the characterization amino acid sequence of a polypeptide "sample molecule" are implied by the term "analyzing".

i) In claim 23, there is no antecedent basis for the term "spec/Ecfunctional groups".

j) For claim 47, it is unclear what is meant by the term "comparatively analyzed". What comparison is being made? What additional method steps are involved in the analysis of "two or more samples"?

k) For claim 52, the recited method steps do not correspond to the preamble "method for labeling" a molecule since no "label" is used in the method.

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/) For claim 52, it is unclear what is meant by the step (b) term "mod/~nqsaidd sample molecule".

9. Claims 1-12, 16, 18-36, 40, 42-50, 52-64, 69 and 71-75 are rejected under judicially created doctrine as being drawn to an improper Markush group. The "solid support coupled to a chemical group" compositions used in the claimed methods' are directed to conjugates comprised of multiple variables recited as a "solid support", a "cleavable functional group", "one or more functional groups" and a "reactive group". These compositions, each of which comprises a composite structure defined by this combination of variables, do not contain a core substantial structure, common to all members of the group, which is essential to the disclosed utility. In the absence of such a structural core common to all of the conjugates, the claims are drawn to improper Markush group.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-12, 16, 18-36, 40, 42-50, 52-64, 69 and 71-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aebersold et al (2005/02333399 A1). Aebersold et al describe a method for labeling and analyzing proteins wherein mass-tagged affinity labeled reagents containing a protein-reactive group (corresponding



to the "chemical group" of claim 1 of this application) are reacted with proteins in a sample to label the proteins {Aebersold et al, paragraphs [0031] and [0032]}. The affinity (e.g. avidin) labeled proteins are then attached to a solid support via affinity binding (e.g. through biotin attached to the solid support). The proteins are then "released from the CR (capture reagent) by... cleavage of the linker" and analyzed by mass spectrometry {paragraph [0031]}. Note that enzymatic cleavage of the protein prior to attachment to the solid support "may not be necessary if the proteins are relatively small".

The Aebersold et al method differs from the claimed methods of this application in attaching the sample to the solid support after reaction of the protein with mass-tag reagent rather than having the mass-tag reagent pre-attached to the solid support prior to reaction of the protein with the reagent as claimed herein. However, this difference in the performance of a sequence of method steps is considered to be *prima facie* obvious in accordance with the discussion of MPEP 2144.04 C. *Changes in Sequence of Adding Ingredients*. Criticality has not been demonstrated for the order of performance of the method steps. The resulting product for both the claimed method and that of Aebersold et al is a mass-tagged protein which has been released from a solid support.

The features of the dependent claims are either specifically described by the references (e.g. for the claim 18 iodoacetyl protein-reactive group, see Aebersold et al, paragraph [006]; for the differential labeling of claim 49, see Aebersold et al paragraph [00741] or constitute obvious variations in parameters which are routinely

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modified in the art (e.g. use of the well known glass bead solid support of claim 30) and which have not been described as critical to the practice of the invention.

### ***Double Patenting***

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-12, 16, 18-36, 40, 42-50, 52-64, 69 and 71-75 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 106-123 of copending Application No. 10/477,619. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter and method steps of copending application are essentially the same as the instant application. Claim 1 of instant application recites a method for labeling a molecule comprising contacting a sample molecule with a

solid support coupled to a chemical group comprising a cleavable functional group and a reactive group and cleaving said cleavable functional group to release said sample molecule. Claim 106 of the copending application (10/477,619) have the same method steps but differ from claim 1 of instant application only by specifying how different components are linked to each other and thus the method of the copending application is obvious over the method of instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusions***

14. No claims are allowed.

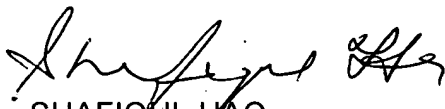
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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